

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: November 13, 1979

SUBJECT: EPA Reg. #524-308; Glyphosate; PP#9F2162; petition proposing establishment of a tolerance for residues of glyphosate and its metabolite in the crop grouping stone fruit at 0.2 ppm. CASWFIL#661A

FROM: William Dykstra
Toxicology Branch (TS-769) WMD 11/13/11 USU

TO: Richard Mountfort Product Manager#25 Residue Chemistry Branch (TS-769)

THRU: Dr. Adrian Gross, Chief fulling S: Butte for M. Edica Gross
Toxicology Branch (TS-769)

Petitioner: Monsanto Agircultural Product, Inc.

800 N. Lindbergh Blvd. St. Louis, Mo. 63166

Recommendations

- 1) The requested tolerance on stone fruit can be toxicologically supported.
- 2) The recommendations of the "free-standing" summary are contained herein.

Section F - It is proposed that following an evaluation of the scientific data supplied with this request and other relevant material, that a tolerance of 0.2 ppm be established for combined residues of the herbicide glyphosate and its metabolite aminomethyl phosphonic acid in or on the raw agricultural commodities stone fruit.

A. Substance Identification

- 1. Chemical Name: Sodium N-(phosphonomethyl) glycine
- 2. Synonyms: MON-8000, Roundup, glyphosate
- 3. Purity of technical material: 98% pure

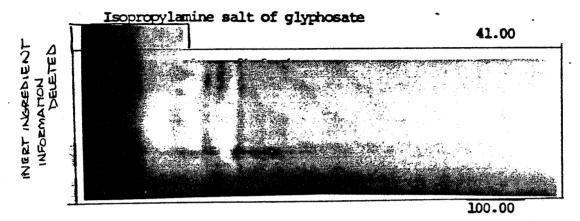
Orto

B. Formulation (Confidential)

Roundup

Ingredient

Percent Weight



Inerts cleared under 180.1001

Review

A. Memo of 8/22/78 from R. Engler to R. Taylor. Toxicology Branch has reviewed the validated studies in support of glyphosate.

1. Data Considered

Oral LD50 Rabbit: 3.8 gm/kg (valid) 090-Day Rat Feeding: NOEL = 2000 ppm (valid) °90-Day Dog Feeding: NOEL = 2000 ppm (valid) OTeratogenic (2 studies) Rabbit: negative at 30 mg/kg/day (highest dose); repeat studies with higher dose °2-Year Dog Feeding: NOEL = 300 ppm (valid) 03-Generation Rat Reproduction: NOEL = 100 ppm (valid) ⁰18-Month Mouse Feeding: no carcinogenic potential at 300 ppm (highest dose); study must be repeated since too many animals are missing. °2-Year Rat Feeding: NOEL = 100 ppm (valid) Study is adequate to determine the toxic effects, but only marginal with respect to oncogenic evaluation since too few animals were examined. As reported the study shows no oncogenic potential. Neurotoxicity (hen): negative at 7.5 mg/kg (camulative for 3 days) (valid) ODominant Lethal (Mice): negative at 10 mg/kg; supplemental study, no records of positive controls. OHOst-Mediated Assay: negative (valid) OAmes-Test: negative (supplemental study), raw data available ORec-Assay: negative (supplemental study), no raw data available.

2. No new toxicity data were submitted with this petition.

3. Evaluation of the ADI

The ADI is based on the NOEL of 100 ppm (5 mg/kg/day) in a 2-year rat feeding study. This is the most sensitive species for which chronic toxicity data are available. A 100 fold safety factor was used to calculate the ADI.

ADI =
$$5 \text{ mg/kg/day} \times \frac{1}{10} = 0.05 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 3.0 mg/day

- 4. Tolerances have been established under 40 CFR 180.364.
- 5. The published tolerances utilize 6.93% of the ADI. Unpublished, TOX approved tolerances utilize the ADI to 10.80%. The current action utilizes 0.13% of the ADI. All tolerances on glyphosate utilize 10.93% of the ADI. (Computer printout is attached).
- 6. No RPAR criteria have been exceeded and no regulatory actions are pending against the pesticide.

Conclusions and Recommendations

The requested tolerance for glyphosate can be toxicologically supported. One of the deficiencies in the glyphosate data base is the lack of an adequate teratology study. It is however concluded that the studies at hand together with the reporduction study show that glyphosate has low potential for showing any teratologic effects. The oncogenic potential of glyphosate is not fully elucidated. The life-time mouse and rat studies, however, provide adequate assurance

that glyphosate has a relatively low oncogenic potential.

A further assurance of low risk associated with glyphosate is found in

A further assurance of low risk associated with glyphosate is found in the fact that on a theoretical basis exposure via the diet is relatively low afpresent.

TOX/HED:th:RD Initial WWOODROW:11-9-79

### ACCEPTABLE DAILY INTAKE DATA ### RAT,Older NOEL	CFR 180.364	Glyphosat	Roundu	P 11/7/79	
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fipI Trinc & ADI 3.0000 mg/day/60kg 0.3241 mg/day/1.5kg 10.30 ***********************************				0.00425	
3.0000 mg/day/50kg 0.3241 mg/day/1.5kg 10.30 ************************** Current Action 9F2162 CROP Tolerance Food Factor mg/day/1.5kg Stone Fruits(151) 0.200 1.25 0.00374	•	0.100	0.06	0.00009	•
Current Action '9F2162 CROP Tolerance Food Factor mg/day/1.5kg Stone Fruits(151) 0.200 1.25 0.00374	11PI 3.0000 mg/day./cov-			& ADI	
Stone Fruits(151) 0.200 1.25 mg/day/1.5kg	*****	********	/day/l.5k *******	10.00	
Stone Fruits(151) 0.200 1.25 mg/day/1.5kg	Current Action 9F216	2	•		•
MDT	CROP TO	lerance Foo	d Factor	ma/day/1 Sea	/
MDT	Stone Fruits(151)	. 200	1.25		
	MPI	47:	190		
3.0000 mg/day/60kg U.3279 mg/day/1.5kg 10.93	3.0000 mg/day/60kg				

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